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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,607	10/03/2001	MALYANKAR M. URIEL	15966-675 CIP 2 (Cura-175	2700

7590 04/26/2005

EXAMINER
MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/26/2005

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/970,607	URIEL, MALYANKAR M.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5, 9-10, 12-14, 80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

1. Claims 1-4, 6-8, 11, 15-79 have been canceled on 2/3/04. Amended claims 10, 12, 14, 80 (4/11/05), original claims 5, 9, 13, are pending and under consideration by the Examiner.

2. Receipt of applicant's arguments and amendments filed on 4/11/2005 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 4/11/2005:

(i) the objection to the title of the invention;

(ii) the rejection of claims 10, 12-13, under 35 USC 112, second paragraph; and

(iii) the rejection of claims 14, 10 and 80 under 35 U.S.C. 112, first paragraph, for scope of enablement; and

(iv) the rejection of claims 5, 9-10, 12-14, 80 under 35 U.S.C. 102(a) and 35 USC 102(e) as being anticipated by WO 01/61009 because priority in the instant application has been afforded to provisional application 60/182, 724, filed 2/15/2000.

4. Applicant's arguments filed on 4/11/2005 have been fully considered and were persuasive in part. The issues remaining are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Applicants request on 4/11/2005 to correct inventorship in a nonprovisional patent application under 37 CFR 1.48(a) and (b) is acknowledged. The current inventors have been deleted and Malyankar, Uriel M. has been added.

Claim Rejections - 35 USC § 101 and § 112

7. Claims 5, 9-10, 12-14, 80 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility.

This rejection is maintained for reasons of record set forth at pages 3-6 of the previous Office action (12/6/2004).

Applicants argue that "for example, the specification states that NOV2 can be used to detect prostate tissue, for diagnostic or therapeutic uses in association with melanoma" (specification page 11, lines 6-14). Applicants then argue that one of skill in the art could follow the teachings in the specification to assess the quantitative differential expression of NOV2 genes in normal and pathological tissues and have cited Example 8, page 129 in the specification, in this regard. Applicants also argue that differential expression of the claimed nucleic acid is "expected" in melanoma cancer tissue. Furthermore, in the specification Applicants disclose that the nucleic acid of the instant invention is useful in the diagnosis of diseases such as prostate cancer, melanoma and diseases of reproductive health (specification page 11, lines 10-14). Therefore, Applicants have admitted on the record, on page 4 of the arguments, that they do not know whether "differential expression of the claimed nucleic acid is obtained in normal and melanoma tissue". This indicates that Applicants are uncertain about differential expression of the instant nucleic acid in normal skin cells and in melanoma. Applicants are arguing on the record, which arguments are insufficient to replace evidence. The PTO has a low threshold for utility and Applicants have still failed to meet this threshold.

The burden of proof is on Applicants to demonstrate that the instant nucleic acid is differentially expressed in normal and cells. Arguments of counsel may be effective in establishing that an examiner has not properly met his or her burden or has otherwise erred in his or her position. However, it must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure. See In re Budnick, 537 F.2d at 538, 190 USPQ at 424; In re Schulze, 346 F.2d 600, 145 USPQ 716 (CCPA 1965); In re Cole, 326 F.2d 769, 140 USPQ 230 (CCPA 1964). For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement. See In re Knowlton, 500 F.2d at 572, 183 USPQ at 37; In re Wiseman, 596 F.2d 1019, 201 USPQ 658 (CCPA 1979). See MPEP 2106.02.

Applicants are required to disclose only one example of a specific, substantial, and well-established utility, and the employment of this nucleic acid only as the subject of further research does not satisfy the utility requirement of 35 U.S.C. 101 because the courts have interpreted this statute as requiring an invention to have a substantial utility where specific benefit exists in currently available form.

Applicants argue that PCT/US02/09808 discloses RTQ-PCR results detecting Hs. 293317 (which is the same as NOV2) in normal and malignant tissue. However, contrary to Applicants arguments, Applicants disclose in the specification that the nucleic acid of the instant invention is useful in the diagnosis of diseases such as prostate cancer, melanoma and diseases of reproductive health (specification page 11, lines 10-14) which are very disparate diseases. Therefore, at the time of filing of the instant application, it was not known to Applicants in

which of these 3 conditions, differential expression of the claimed nucleic acid would be specifically obtained. Furthermore, an application has to be complete as filed, it is not a starting point of further research. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicants claimed invention is incomplete.

With respect to the instant nucleic acid, Applicants argue that the specific assertion that the claimed nucleic acid may be used for diagnosis of disorders such as melanoma, warrants utility. However, applicants have failed to demonstrate differential expression of the claimed protein in normal and melanoma cells. Therefore, the disclosure that this nucleic acid can be used in diagnosis is not useful information at the time of the invention since one has no idea of whether the nucleic acid is differentially expressed in cancerous skin cells relative to normal skin cells.

The following is an excerpt from M.P.E.P. 2138.05:

ACLAIMED INVENTION IS NOT ACTUALLY REDUCED TO PRACTICE UNLESS THERE IS A KNOWN UTILITY

Utility for the invention must be known at the time of the reduction to practice. Wiesner v. Weigert , 212 USPQ 721, 726 (CCPA 1981) (except for plant and design inventions); Azar v. Burns , 188 USPQ 601, 604 (Bd. Pat. Inter. 1975) (a composition and a method cannot be actually reduced to practice unless the composition and the product produced by the method have a practical utility); Ciric v. Flanigen , 185 USPQ 103, 105 - 6 (CCPA 1975) ("when a count does not recite any particular utility, evidence establishing a substantial utility for any purpose is sufficient to prove a reduction to practice"; "the demonstrated similarity of ion exchange and adsorptive properties between the newly discovered zeolites and known crystalline zeolites ... have established utility for the zeolites of the count"); Engelhardt v. Judd , 151 USPQ 732, 735 (CCPA 1966) (When considering an actual reduction to practice as a bar to patentability for claims to compounds, it is sufficient to successfully demonstrate utility of the compounds in animals for somewhat different pharmaceutical purposes than those asserted in the specification for humans.); Rey - Bellet v. Engelhardt,181 USPQ 453, 455 (CCPA 1974) (Two categories of tests on laboratory animals have been considered adequate to show utility and reduction to practice: first, tests carried out to prove utility in humans where there is a satisfactory correlation between humans and animals, and second, tests carried out to prove utility for treating animals.).

A PROBABLE UTILITY MAY NOT BE SUFFICIENT TO ESTABLISH UTILITY

A probable utility does not establish a practical utility, which is established by actual testing or where the utility can be "foretold with certainty." Bindra v. Kelly , 206 USPQ 570, 575 (Bd. Pat. Inter. 1979) (Reduction to practice was not established for an intermediate useful in the preparation of a second intermediate with a known utility in the preparation of a pharmaceutical. The record established there was a high degree of probability of a successful preparation because one skilled in the art may have been motivated, in the sense of 35 U.S.C. 103, to prepare the second intermediate from the first inter mediate. However, a strong probability of utility is not sufficient to establish practical utility.); Wu v. Jucker , 167 USPQ 467, 472 (Bd. Pat. Inter. 1968) (screening test where there was an indication of possible utility is insufficient to establish practical utility). But see Nelson v. Bowler , 206 USPQ 881, 885 (CCPA 1980) (Relevant evidence is judged as a whole for its persuasiveness in linking observed properties to suggested uses. Reasonable correlation between the two is sufficient for an actual reduction to practice.).

Therefore Applicants have failed to establish a practical utility for the protein of the instant invention at the time the application was filed.

Claims 5, 9-10, 12-14, 80, are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. There is no specific and substantial asserted utility or well established utility for the claimed nucleic acid.

Claim rejections-35 USC § 112, second paragraph

8. Claim 80 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 80 is vague and indefinite because it has been amended to be dependent on independent claim 5 and claim 5 encompasses a nucleic acid, which encodes a polypeptide of amino acid sequence set forth in SEQ ID NO:4, however, it is inconceivable that the complement

of the nucleic acid encode such a protein. Therefore, it is suggested that claim 80 be amended and written as an independent claim to recite a complement of a nucleic acid molecule wherein said nucleic acid molecule comprises SEQ ID NO:3.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
April 21, 2005